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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/629,291 | 07/28/2003 | Guangqiang Jiang | A329-USA | 6474 |
| 24677 | 7590 | 03/24/2008 | | |
| ALFRED E. MANN FOUNDATION FOR SCIENTIFIC RESEARCH PO BOX 905 SANTA CLARITA, CA 91380 | | | EXAMINER | |
| | | | GEDEON, BRIAN T | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3766 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 03/24/2008 PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/629,291

Applicant(s)

JIANG ET AL.

Examiner

Brian T. Gedeon

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-28 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-3 and 5-28 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 January 2008 has been entered.

Claim Objections

2. The objection to claim 5 has been withdrawn in view of the amendment submitted with the RCE.

Response to Arguments

3. Applicant's arguments with respect to claims 1-3 and 5-28 have been considered but are moot in view of the new ground(s) of rejection. The new grounds of rejection follow below.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3, 5-7, 10-16, 19, 23, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chatterjee et al. (US Patent no. 5,677,072) in view of Whitehurst et al. (US Patent no. 6,735,475).

In regard to claims 1, 10, 13, 19, and 23, Chatterjee et al. disclose a method for producing a long-lived, stabilized tetragonal zirconia polycrystal ceramic, col 2 lines 24-27 and col 4 lines 46-50, comprising the step of hot isostatic pressing said ceramic at a controlled temperature, at a controlled pressure, col 7 lines 25-32 and lines 38-48, and in a controlled atmosphere to achieve an average grain size of less than about 0.5 micron, col 4 lines 29-34, to substantially eliminate open porosity and to increase bulk density to about 100%, col 7 lines 10-13, of theoretical, thereby substantially eliminating low-temperature degradation of said polycrystal ceramic. However, Chatterjee et al. does not teach the use of the ceramic material to be used as a housing for an implantable medical device, though does teach that the ceramic article produced can take the form of any predetermined shape or dimension, col 4 lines 54-61. Whitehurst et al. disclose a microstimulator, known as the BION, col 8 lines 31-34, with a housing that can be fabricated from ceramic, col 16 lines 1-3, with dimensions of 3-5 mm or less in diameter, 20-35 mm or less in length, col 15 lines 50-53, wherein the microstimulator housing is a thin elongated cylinder, col 15 lines 56-59. The microstimulator may be inserted into a patient via a hypodermic syringe, col 15 lines 60-62. Therefore it would

have been obvious to one of ordinary skill in the art at the time the invention was made to use the ceramic formed by Chatterjee et al. as a microstimulator housing since Whitehurst et al. teach that microstimulator housings can be made from ceramic, and Chatterjee et al. suggest that the product produced can be dimensioned and shaped in any predetermined form. Further the modification of Chatterjee et al. in view of Whitehurst et al. would be obvious to one of ordinary skill in the art since known work in one field of endeavor may prompt variations of it for use in either the same field of a different one based on design incentives if the variations are predictable to one of ordinary skill in the art.

In regard to claims 2, 3, 11, and 12, the tetragonal zirconia polycrystal of Chatterjee et al. is stabilized with between 1.5 to 5 mol percent Ytria, col 4 lines 47-49.

In regard to claims 5 and 14, Whitehurst et al. describe a implantable microstimulator housing with dimensions of 3-5 mm or less in diameter, 20-35 mm or less in length, col 15 lines 50-53, wherein the microstimulator housing is a thin elongated cylinder, col 15 lines 56-59. It would have been obvious to one with ordinary skill in the art at the time the invention was made to utilize 100 mm or less for length, 10 mm or less for diameter, and 2 mm or less for wall thickness of the claimed tube since our reviewing courts have held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469

U.S. 830, 225 USPQ 232 (1984). It is also well known in the art that the dimensions of the BION microstimulator, which is the embodiment of the Whitehurst et al., are of the millimeter scale or smaller.

In regard to claims 6, 15, 21, and 25, the sintering process of Chatterjee et al. is controlled at a temperature between 1300⁰ C to 1600⁰ C, col 7 lines 38-48.

In regard to claims 7, 16, 20, and 26, the sintering process of Chatterjee et al. is controlled at a pressure between 50 to 200 MPa, col 7 lines 25-32.

6. Claims 8, 9, 17, 18, 22, 24, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chatterjee et al. (US Patent no. 5,677,072) in view of Whitehurst et al. (US Patent no. 6,735,475), further in view of Tsukuma et al. (US Patent no. 4,587,225).

In regard to claims 8, 9, 17, 18, 22, 27, and 28, Chatterjee et al. in view of Whitehurst et al. substantially describe the invention as claimed except for the controlled atmosphere conditions of a hot isostatic processing of the ceramic material. Tsukuma et al. is reference to provide the teaching that hot isostatic pressing processes for producing a tetragonal zirconia polycrystal ceramic is controlled at an atmosphere in argon, col 8 lines 61-66. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the process for making a ceramic tube described by Chatterjee et al. in view of Whitehurst et al. since it would involve applying a known technique in the art to a known process to yield predictable results.

In regard to claim 24, the ceramic of Tsukuma et al. has a three point bending stress of at least 1700 MPa, col 3 lines 21-35.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272-3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

Carl H. Layno
Examiner
Art Unit 3766

/B. T. G./

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